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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,449	04/01/2004	Yvo Graus	21655 US2	8584
151 7590 07/25/2007 HOFFMANN-LA ROCHE INC. PATENT LAW DEPARTMENT 340 KINGSLAND STREET NUTLEY, NJ 07110			EXAMINER DANG, IAN D	
			ART UNIT 1647	PAPER NUMBER
			MAIL DATE 07/25/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/815,449	<b>Applicant(s)</b> GRAUS ET AL.	
	<b>Examiner</b> Ian Dang	<b>Art Unit</b> 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-11 and 23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4-11 is/are rejected.
- 7) ☒ Claim(s) 23 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>03/09/2007</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of Application, Amendments and/or Claims***

The amendment of 02 May 2007 has been entered in full. Claims 3, and 12-22 have been cancelled and claims 1, 4-5, and 11 have been amended. Claim 23 is added.

Claims 1-2, 4-11, and 23 are pending and under examination.

### ***Claim Objections***

Applicant's amendments to claims 4 and 5 (see page 6) filed on 05/02/2007 have overcome the objections of claims 4 and 5. The objection of claims 4 and 5 has been withdrawn.

### ***35 USC § 112 (Biological Deposit Rule)***

Applicant's response and arguments (see page 6) filed on 05/02/2007 have overcome the rejection of claim 10 under 35 U.S.C. § 112, First paragraph. The rejection of claim 10 under 35 U.S.C. § 112, First paragraph has been withdrawn.

### ***35 USC § 112, first paragraph (Enablement)***

Applicant's response, arguments (see page 7), and cancellation of claim 3 filed on 05/02/2007 have overcome the rejection of claims 1-11 under 35 U.S.C. § 112, First paragraph (enablement). The rejection of claims 1-11 under 35 U.S.C. § 112, First paragraph has been withdrawn.

### ***35 USC § 112, second paragraph***

Applicant's response and amendments to claim 1 (see page 10) filed 05/02/2007 have

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overcome the rejection of claims 1-11 under 35 U.S.C. § 112, Second paragraph. The rejection of claims 1-11 under 35 U.S.C. § 112, Second paragraph has been withdrawn.

**35 USC § 102**

Applicant's response, arguments, and cancellation of claim 3 filed on 05/02/2007 have overcome the rejection of claims 1, and 3-5 under 35 U.S.C. § 102(a). The rejection of claims 1 and 3-5 under 35 U.S.C. § 102(a) has been withdrawn.

**35 USC § 103**

Applicant's response, arguments, and cancellation of claim 3 filed on 05/02/2007 have overcome the rejection of claims 1, 2, 6, and 11 under 35 U.S.C. § 103(a). The rejection of claims 1, 2, 6, and 11 under 35 U.S.C. § 103(a) has been withdrawn.

***Claim Objections***

Claim 23 is objected to because of the following informalities:

Claim 23 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Appropriate correction is required.

### **New Ground of Rejections**

#### ***Claim Rejections - 35 USC § 101-non-statutory subject matter***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-2, 4-10 are rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter.

The claims read on a product of nature in that the claimed antibody is not "isolated". For example, the claims encompass polyclonal sera that has not been removed from a human. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "isolated" or "purified". See MPEP 2105.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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Claims 1, 4, 5 and 11 are rejected under 35 U.S.C. 102(a) and 35 U.S.C. 102(e) as being anticipated by Cohen et al., (WO 02/053596 A2, filed 12/20/2001, and published 07/11/2002, cited in the IDS filed 02/03/2005).

Cohen et al., teach a human or humanized antibody (page 14, line 21) binding to IGF-IR that inhibits the binding of IGF-I and IGF-II to IGF-IR (page 8, lines 6-9) and that the antibody is an IgG1 isotype (page 24, line 12), meeting the limitations of claim 1. Although the reference is silent upon a ratio of IC50s for the inhibition of the binding of IGF-I and IGF-II to IGF-IR of 1:3 to 3:1 and that the antibody induces cell death of a preparation of IGF-IR expressing cells in an antibody dependent cellular toxicity assay or in a complement dependent cytotoxicity (CDC) assay, the teachings of the reference would inherently result in this outcome because a compound and all of its properties are inseparable; they are one and the same thing (see *In re Papesch*, CCPA 137 USPQ 43; *In re Swinehart and Sfiligoj*, 169 USPQ 226 (CCPA 1971)). The antibody of Cohen et al. inherently performs the function required by the claims of the instant case, absent evidence to the contrary (*In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977)).

In addition, Cohen et al. teach that the antibody binds IGF-IR with an affinity of about  $10^{-11}$  to  $10^{-8}$  M ( $K_D$ ) and of about  $10^{-11}$  to  $10^{-9}$  M ( $K_D$ ) (page 25, lines 19 to 23) meeting the limitations of claims 4 and 5. Furthermore, Cohen et al. teach that a composition comprising the antibody of the invention and pharmaceutically acceptable carrier (page 57, line 1) meeting the limitations claim 11.

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### Conclusion

No claim is allowed.

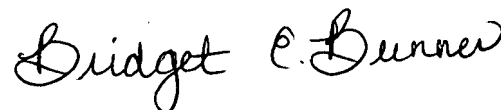
### Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ian Dang whose telephone number is (571) 272-5014. The examiner can normally be reached on Monday-Friday from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ian Dang  
Patent Examiner  
Art Unit 1647  
July 18, 2007



BRIDGET E. BUNNER  
PRIMARY EXAMINER